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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/560,103	03/14/2007	Kelly M. McNagny	7685-102	4592

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EXAMINER	
HALVORSON, MARK	
ART UNIT	PAPER NUMBER
1642	

MAIL DATE	DELIVERY MODE
10/15/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/560,103	MCNAGNY ET AL.	
	Examiner	Art Unit	
	Mark Halvorson	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *09 December 2005*.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-33* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-33* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-33 are pending.

Election/Restrictions

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group 1, claim(s) 1, 2, 5-10 drawn to a method of detecting cancer in a patient comprising determine the level of podcalyxin.

Group 2, claim(s) 1, 3, 5-10, drawn to a method of detecting cancer in a patient comprising determine the level of endoglycan.

Group 3, claim(s) 1, 4-11, drawn to drawn to a method of detecting cancer in a patient comprising determine the level of podocalyxin and endoglycan.

Group 4, claim(s) 12, drawn to drawn to drawn to a method of determining whether or not a cancer is metastatic comprising determine the level of podocalyxin..

Group 5, claim(s) 12, drawn to drawn to a method of determining whether or not a cancer is metastatic comprising determine the level of endoglycan.

Group 6, claim(s) 12 and 13, drawn to drawn to a method of determining whether or not a cancer is metastatic comprising determine the level of podocalyxin and endoglycan..

Group 7, claim(s) 14 and 15, drawn to a kit comprising nucleic acid primers for amplifying mRNA encoding endoglycan.

Group 8, claim(s) 14 and 15, drawn to a kit comprising nucleic acid primers for amplifying mRNA encoding podocalyxin.

Group 9, claim(s) 14 and 15, drawn to a kit comprising nucleic acid primers for amplifying mRNA encoding podocalyxin and endoglaycan.

Group 10, claim(s) 14 and 16, drawn to a kit comprising antibodies specific for podocalyxin.

Group 11, claim(s) 14 and 16, drawn to a kit comprising antibodies specific for endoglycan.

Group 12, claim(s) 14 and 16, drawn to a kit comprising antibodies specific for podocalyxin and endoglycan.

Group 13, claim(s) 24 and 26, drawn to a method for identifying a compound that modulates podocalyxin comprising incubating a test compound with the protein podocalyxin.

Group 14, claim(s) 24 and 26, drawn to a method for identifying a compound that modulates podocalyxin comprising incubating a test compound with a nucleic acid encoding podocalyxin.

Group 15, claim(s) 25 and 27, drawn to a method for identifying a compound that modulates endoglycan comprising incubating a test compound with the protein endoglycan.

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Group 16, claim(s) 25 and 27, drawn to a method for identifying a compound that modulates endoglycan comprising incubating a test compound with a nucleic acid encoding endoglycan.

Group 17, claim(s) 28 and 29, drawn to a pharmaceutical composition comprising an effective amount of a podocalyxin modulator.

Group 18, claim(s) 30 and 31, drawn to a pharmaceutical composition comprising an effective amount of an endoglycan modulator.

Group 19, claim(s) 32 and 33, drawn to drawn to a pharmaceutical composition comprising an effective amount of a podocalyxin modulator and a endoglycan modulator.

Claims 17-23 are withdrawn from consideration because these claims are use claims and it is unclear what method/process applicant is intending to encompass. Upon amendment, the claims will be rejoined to or restricted to the appropriate group.

A national stage application shall relate to one invention only or to a group of inventions so linked as to form a single general inventive concept. Unity of invention is fulfilled only when there is a technical relationship among the inventions involving one or more of the same or corresponding, special technical features which define a contribution over the prior art. If there is no special technical feature, if multiple products, processes of manufacture or uses are claimed, the first invention of the category first mentioned in the claims of the application will be considered as the main invention in the claims, see PCT article 17(3)(a) and 1.476(c), 37 C.F.R. 1.475(d)

The invention listed as Groups 1-6 do not relate to a single inventive concept under PCT Rule 1.31 because, under PCT 13.2 they lack the same or corresponding special technical feature for the following reasons:

The technical feature of claim 1 is a method of detecting cancer in a patient comprising determining the level of podocalyxin and/or endoglycan in a sample from the patient; and comparing the level of podocalyxin and/or endoglycan in the sample to a control sample, wherein increased levels of podocalyxin and/or decreased levels of endoglycan as compared to the control indicates that the patient has cancer.

Xu et al (US Patent No: 6,613,515, issued Sept 2, 2003, filed Aug 15, 2000)discloses that podocalyxin is overexpressed in ovarian carcinoma tissues (Table VI). Thus, Claim 1 lacks the special technical feature.

Thus, the different groups in the present application do not contain a single inventive concept and puts a serious search burden on the Examiner.

Inventions 1-3, 4-6, 7-9, 10-12, and 17-19 are related as subcombinations disclosed as usable together in a single combination. The subcombinations are distinct if they do not overlap in scope and are not obvious variants, and if it is shown that at least one subcombination is separately usable. In the instant case, subcombinations of Inventions1, 4, 7, 10 and 17 would have separate utility than subcombinations of Inventions 2, 5, 8, 11 and 18. See MPEP § 806.05(d).

The examiner has required restriction between subcombinations usable together. Where applicant elects a subcombination and claims thereto are subsequently found allowable, any claim(s) depending from or otherwise requiring all the limitations of the allowable subcombination will be examined for patentability in accordance with 37 CFR 1.104. See MPEP § 821.04(a). Applicant is advised that if any claim presented in a continuation or divisional application is anticipated by, or includes all the limitations of, a claim that is allowable in the present application, such claim may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application.

Inventions 1-3, 4-6, 7-9, 10-12, and 17-19 are related as combination and subcombination. Inventions in this relationship are distinct if it can be shown that (1) the combination as claimed does not require the particulars of the subcombination as claimed for patentability, and (2) that the subcombination has utility by itself or in other

combinations (MPEP § 806.05(c)). In the instant case, the combination as claimed does not require the particulars of the subcombination as claimed because each subcombination has separate utility. The subcombination in Inventions 1, 4, 7, 10, and 17 have separate utilities. For example, an antibody to endoglycan would have a separate utility than an antibody to podocalyxin. Modulators of endoglycan would have different utilities than modulators of podocalyxin.

The examiner has required restriction between combination and subcombination inventions. Where applicant elects a subcombination, and claims thereto are subsequently found allowable, any claim(s) depending from or otherwise requiring all the limitations of the allowable subcombination will be examined for patentability in accordance with 37 CFR 1.104. See MPEP § 821.04(a). Applicant is advised that if any claim presented in a continuation or divisional application is anticipated by, or includes all the limitations of, a claim that is allowable in the present application, such claim may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application.

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed to a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP

§ 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder**. Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mark Halvorson, PhD whose telephone number is (571) 272-6539. The examiner can normally be reached on Monday through Friday from 8:30am to 5 pm. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms, can be reached at (571) 272-0832. The fax phone number for this Art Unit is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Mark Halvorson/
Examiner, Art Unit 1642